UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/613,092	07/10/2000	Edwin W. Ades	68430	9419

23859 7590 09/17/2002

NEEDLE & ROSENBERG P C
127 PEACHTREE STREET N E
ATLANTA, GA 30303-1811

EXAMINER
DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
1645	13

DATE MAILED: 09/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/613,092	Applicant(s) Ades et al.
	Examiner S. Devi, Ph.D.	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 23, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above, claim(s) *2-10 and 12-20* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1 and 11* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *5.*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Preliminary Amendment

1) Acknowledgment is made of preliminary amendment filed 10/15/01 (paper no. 9).

Election

2) Acknowledgment is made of Applicants' election, with traverse, of invention 9, claim 11, filed 07/23/02 (paper no. 11) in response to the restriction requirement mailed 07/03/02 (paper no. 10).

The Applicants' traversal is on the grounds that the Office has not shown that a serious burden would be required to examine all the claims. Applicants cite MPEP 803 and state that two criteria, i.e., the existence of independent and distinct inventions and the search and examination of the entire application cannot be made without serious burden. Applicants state that the Office has not shown that the second requirement has been met. Applicants further assert that the restriction requirement is discretionary and is contrary to promoting efficiency, economy and expediency in the U.S. Patent and Trademark Office (PTO). Applicants request that invention 15 be rejoined with invention 9.

The Applicants' argument has been carefully considered, but is not persuasive. The requirement of 35 U.S.C. 121 is that a patent application be directed to only a single invention. If more than one invention is included in the application, the Examiner can require the application to be restricted to one of the inventions. As clearly set forth in the restriction requirement mailed 07/08/02 (paper no. 9), invention 9 and 15 are related as product and process of using the product of invention I. M.P.E.P 806.05(h) permits the Office to separate the product from the process of using the product by showing that the process of using the product can be used to make a materially different product, such as, an *in vitro* diagnostic reagent or composition. However, claim 19 will be retained as a pending claim pursuant to the rejoinder provisions of M.P.E.P 821.04 and will be withdrawn from consideration until such time as the subject matter of claim 11 is deemed allowable. The Examiner in charge of the instant application will then determine if claim 19 includes all of the limitations of the allowable product claim and is of the same scope as allowable product claim, prior to determining if rejoinder will be permitted under M.P.E.P 821.04. With regard to the Applicants' argument that the Office has

not established the existence of a serious burden to search, as set forth in the restriction requirement mailed 0703/02, inventions 1-11 are drawn to different peptides or peptide combinations which are structurally, biologically or immunogenically distinct from one another, requiring separate searches that are non-coextensive. For these reasons, the restriction requirement mailed 07/03/02 is maintained and is hereby made FINAL.

Status of Claims

3) Claims 1-20 are pending.

Claims 2-10 and 12-20 have been withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

The elected claim 11 and the linking claim 1 are under examination. An Action on the Merits for these claims is issued.

Sequence Listing

4) Acknowledgment is made of Applicants' submission of the raw sequence listing and CRF which has been entered.

Information Disclosure Statement

5) Acknowledgment is made of Applicants' information disclosure statement filed 10/23/00 (paper no. 5). The information referred to therein has been considered and a signed copy of the same is attached to this Office Action (paper no. 13).

Drawings

6) The drawings submitted in the instant application are not objected to by the Draftsperson under 37 C.F.R 1.84 or 1.152 and as such, the drawings have been approved as formal drawings.

Co-pending Application

7) At the time this Office Action was written, a co-pending application, SN 09/754,809, was not available to the Examiner of record for review. Applicants' assistance is requested in providing the Office with a copy of pending claims from the co-pending application. Applicants are advised that any pending or allowed application claiming the instantly claimed composition may serve as a ground for a double patenting rejection in the next Office Action.

Specification - Informalities

8) The specification is objected to for the following reasons:

(a) The use of the trademarks in the instant specification has been noted in this application. For example, see page 60, line 4; page 38, line 15; page 35, lines 25 and 28; and page 36, line 27: "Tween 20"; page 67, line 16 "Sequanase"; page 38, line 14: "Triton X-100"; page 37, line 23: "Dialux 20"; page 38, lines 2 and 3: "Lowicryl"; page 60, lines 1 and 2: "Nunc ... MaxiSorb"; and page 28, line 14: "alhydrogel". Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification and make necessary changes wherever trademark recitations appear.

(b) It is unclear whether or not the recitation "CYGG" on page 29, line 9 and page 28, line 27 and the recitation "LXCC" on page 51, line 18 and page 49, line 29 represent an amino acid sequence. If so, Applicants are required to comply with Sequence Rules by identifying the sequences by a SEQ ID Number and include the sequences in the raw sequence listing as well as in a CRF for submission. Any additional sequences recited in the instant specification which are encompassed by the definitions for nucleotide and/or amino acid sequences as set forth in 37 C.F.R. 1.821(a)(1) and (a)(2) must comply with the requirements of 37 C.F.R 1.821 through 1.825. APPLICANTS MUST COMPLY WITH THE SEQUENCE RULES WITHIN THE SAME TIME PERIOD AS IS GIVEN FOR RESPONSE TO THIS ACTION, 37 C.F.R 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R 1.136. In no case may an Applicant extend the period of reply beyond the SIX MONTH statutory period. Applicants are requested to return a copy of the attached Notice to Comply with the response.

Rejection(s) under Double Patenting

9) The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970) and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R 3.73(b).

Instant claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-6, 8-12, 18 and 20 of the application SN 09/623,038. Instant claim 11 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 6, 12 and 20 of the application SN 09/623,038. Although the conflicting claims are not identical, they are not patentably distinct from each other because of their overlapping scope.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Rejection(s) under 35 U.S.C. § 101

10) Claim 1 is rejected under as 35 U.S.C § 101 as being directed to a non-statutory subject matter. The claim encompasses a peptide and therefore reads on products of nature, i.e., naturally occurring peptide. The claim lacks limitations which distinguish this product from those that may exist naturally. Consequently, the claim does not embody patentable subject matter as defined in 35 U.S.C § 101. See MPEP 2105. The rejection can be obviated by amending claim 1 to recite --An isolated peptide-- in connection with the product to reflect the hands of the inventors in the production or creation of the recited product if such a recitation has descriptive support in the specification, as originally filed.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

11) Claims 1 and 11 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite

for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 1 is vague and indefinite in the abbreviated recitation "PsaA" in the claim language. It is suggested that the abbreviation be recited as a full terminology at first occurrence in the base claim, with its abbreviated recitation retained in parentheses.

(b) Claim 11 is vague in the recitation "comprising SEQ ID NO: ...." without reciting that the sequence is an amino acid sequence. In order to distinctly claim the subject matter of the instant invention, it is suggested that Applicants replace the recitation with --comprising the amino acid sequence of SEQ ID NO: ...--.

(c) Claim 11 is vague and indefinite in the recitations: at least one "first arm"; "second arm" and "third arm", because it is unclear what is encompassed in the recitation "arm". Does the recitation arm represent a 'part' or 'portion' of the peptide, or a branch of the peptide?

Rejection(s) under 35 U.S.C. § 102

12) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> **(a)** the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> **(b)** the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13) Claim 1 is rejected under 35 U.S.C § 102(b) as being anticipated by De *et al.* (*Pathobiology* 67: 115-122, May-June 1999).

De *et al.* teach a recombinant PsaA polypeptide (i.e., a multiple antigenic peptide) which specifically binds to an anti-PsaA monoclonal antibodies obtained from an animal against *Streptococcus pneumoniae* PsaA. That the prior art polypeptide inherently contains multiple epitopes and serves as a multiple antigenic peptide is inherent from the teachings of De *et al.*

Claim 1 is anticipated by De *et al.*

14) Claims 1 and 11 are rejected under 35 U.S.C § 102(a) as being anticipated by Ades *et al.* (WO 99/45121 - Applicants' IDS) ('121).

It is noted that the prior art patent '121 lists Tharpe JA, Westerink MAJ and Zeiler JL as co-inventors and therefore qualifies as prior art by 'another' under 35 U.S.C § 102(a).

Since the instant specification does not provide a precise definition for the recitation "arm" in claim 11, this limitation is broadly interpreted as a part of the claimed peptide.

Ades *et al.* disclose a peptide that immunospecifically binds to a monoclonal antibody obtained in response to immunizing an animal with *Streptococcus pneumoniae* PsaA. The peptide comprises the amino acid sequences of SEQ ID N: 5, 6 and 7 (see claims 12-15 and 20; and page 19). That the prior art peptide serves as a multiple antigenic peptide is inherent from the teachings of Ades *et al.* A sequence search performed at the Office has shown that Aedes' peptides show 100% sequence identity with the instantly claimed SEQ ID NO: 5, 6 and 7. See the attached sequence search reports.

Claims 1 and 11 are anticipated by Ades *et al.* ('121).

Remarks

15) Claims 1 and 11 stand rejected.

16) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

17) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SD
S. DEVI, PH.D.
PRIMARY EXAMINER
Septem. 02

SEQ ID NO. 7

RESULT 1
AAY30353
ID AAY30353 standard; Peptide; 15 AA.
XX
AC AAY30353;
XX
DT 09-NOV-1999 (first entry)
XX
DE Epitope derived from pneumoccocal surface adhesion A protein.
XX
KW Pneumoccocal surface adhesion A protein; PsaA; monoclonal antibody;
KW vaccine; Streptococcus pneumoniae infection.
XX
OS Streptococcus pneumoniae.
XX
PN WO9945121-A1.
XX
PD 10-SEP-1999.
XX
PF 26-FEB-1999; 99WO-US04326.
XX
PR 02-MAR-1998; 98US-0076565.
XX
PA (USSH) US DEPT HEALTH & HUMAN SERVICES.
XX
PI Ades EW, Carlone GM, Sampson JS, Tharpe JA, Westerink MAJ;
PI Zeiler JL;
XX
DR WPI; 1999-540849/45.
XX
PT New peptides corresponding to Streptococcus pneumoniae PsaA, used
PT for treating or preventing Streptococcus pneumoniae infection in a
PT subject
XX
PS Claim 6; Page 43; 58pp; English.
XX
CC AAY30351-54 represent immunogenic peptides which are derived from
CC a pneumoccocal surface adhesion A protein (PsaA). The specification
CC describes monoclonal antibodies which bind epitopes of the PsaA protein
CC (e.g present sequence). The peptides can be used in vaccines to prevent
CC Streptococcus pneumoniae infections. The antibodies of the invention
CC can also be used to detect S. pneumoniae in a sample or individual.
XX
SQ Sequence 15 AA;

Query Match 100.0%; Score 79; DB 20; Length 15;
Best Local Similarity 100.0%; Pred. No. 2e-07;
Matches 15; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 LVRRFVHRRPHVESQ 15
||||||||||||||||
Db 1 lvrrfvhrrphvesq 15

Db 1 lvrr

RESULT 3
AAB75292
ID AAB75292
XX
AC AAB75292;
XX
DT 03-APR-20
XX
DE Gene 6 hu
XX
KW Human; im
KW antiproli
KW neuroprot
KW vulnerary
KW cardiovas
KW nervous s
KW secreted

ALIGNMENTS

SEQ ID NO.6

```
RESULT   1
AAY30352
ID   AAY30352 standard; Peptide; 15 AA.
XX
AC   AAY30352;
XX
DT   09-NOV-1999  (first entry)
XX
DE   Epitope derived from pneumoccocal surface adhesion A protein.
XX
KW   Pneumoccocal surface adhesion A protein; PsaA; monoclonal antibody;
KW   vaccine; Streptococcus pneumoniae infection.
XX
OS   Streptococcus pneumoniae.
XX
PN   WO9945121-A1.
XX
PD   10-SEP-1999.
XX
PF   26-FEB-1999;   99WO-US04326.
XX
PR   02-MAR-1998;   98US-0076565.
XX
PA   (USSH ) US DEPT HEALTH & HUMAN SERVICES.
XX
PI   Ades EW, Carlone GM, Sampson JS, Tharpe JA, Westerink MAJ;
PI   Zeiler JL;
XX
DR   WPI; 1999-540849/45.
XX
PT   New peptides corresponding to Streptococcus pneumoniae PsaA, used
PT   for treating or preventing Streptococcus pneumoniae infection in a
PT   subject
XX
PS   Claim 6; Page 43; 58pp; English.
XX
CC   AAY30351-54 represent immunogenic peptides which are derived from
CC   a pneumoccocal surface adhesion A protein (PsaA). The specification
CC   describes monoclonal antibodies which bind epitopes of the PsaA protein
CC   (e.g present sequence). The peptides can be used in vaccines to prevent
CC   Streptococcus pneumoniae infections. The antibodies of the invention
CC   can also be used to detect S. pneumoniae in a sample or individual.
XX
SQ   Sequence   15 AA;

  Query Match             100.0%;  Score 87;  DB 20;  Length 15;
  Best Local Similarity   100.0%;  Pred. No. 6.9e-08;
  Matches   15;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy       1 RSYQHDLRAYGFWRL 15
           |||||||||||||||
Db       1 rsyqhdlraygfwrl 15
```

```
CC   responsible f
CC   and to produc
CC   amino acid se
CC   diagnostic am
CC   Note: The seq
CC   specification
CC   at ftp.wipo.i
XX
SQ   Sequence   55

  Query Match
  Best Local Simil
  Matches    7;  C

Qy       3 YQHDLRAY
           |:| | ||
Db       7 ykhslhay
```

SEQ ID NO.5

```
RESULT  1
AAY30351
ID   AAY30351 standard; Peptide; 15 AA.
XX
AC   AAY30351;
XX
DT   09-NOV-1999  (first entry)
XX
DE   Epitope derived from pneumoccocal surface adhesion A protein.
XX
KW   Pneumoccocal surface adhesion A protein; PsaA; monoclonal antibody;
KW   vaccine; Streptococcus pneumoniae infection.
XX
OS   Streptococcus pneumoniae.
XX
PN   WO9945121-A1.
XX
PD   10-SEP-1999.
XX
PF   26-FEB-1999;   99WO-US04326.
XX
PR   02-MAR-1998;   98US-0076565.
XX
PA   (USSH ) US DEPT HEALTH & HUMAN SERVICES.
XX
PI   Ades EW,  Carlone GM,  Sampson JS,  Tharpe JA,  Westerink MAJ;
PI   Zeiler JL;
XX
DR   WPI; 1999-540849/45.
XX
PT   New peptides corresponding to Streptococcus pneumoniae PsaA, used
PT   for treating or preventing Streptococcus pneumoniae infection in a
PT   subject
XX
PS   Claim 6; Page 43; 58pp; English.
XX
CC   AAY30351-54 represent immunogenic peptides which are derived from
CC   a pneumoccocal surface adhesion A protein (PsaA). The specification
CC   describes monoclonal antibodies which bind epitopes of the PsaA protein
CC   (e.g present sequence). The peptides can be used in vaccines to prevent
CC   Streptococcus pneumoniae infections. The antibodies of the invention
CC   can also be used to detect S. pneumoniae in a sample or individual.
XX
SQ   Sequence   15 AA;


  Query Match             100.0%;  Score 91;  DB 20;  Length 15;
  Best Local Similarity   100.0%;  Pred. No. 3.8e-07;
  Matches   15;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy       1 TVSRVPWTAWAFHGY 15
           |||||||||||||||
Db       1 tvsrvpwtawafhgy 15
```